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(54) Vaginal autosuture device

(57) A vaginal autosuture device to treat urinary incontinence in women is disclosed. The device comprises an elongate body 10 having at one of its ends an extension at a specific angle to the horizontal axis of the body. The extension defines a head 11 through which and by means of actuating a manual control 13 a clamp is released or, in other embodiments, a threaded needle is turned. The clamp or threaded needle pass through the para-urethral tissue and the cartilage of the symphysis pubica effecting a connection and lifting of the corresponding areas of the vagina located on both sides of the urethra thus avoiding urinary incontinence.

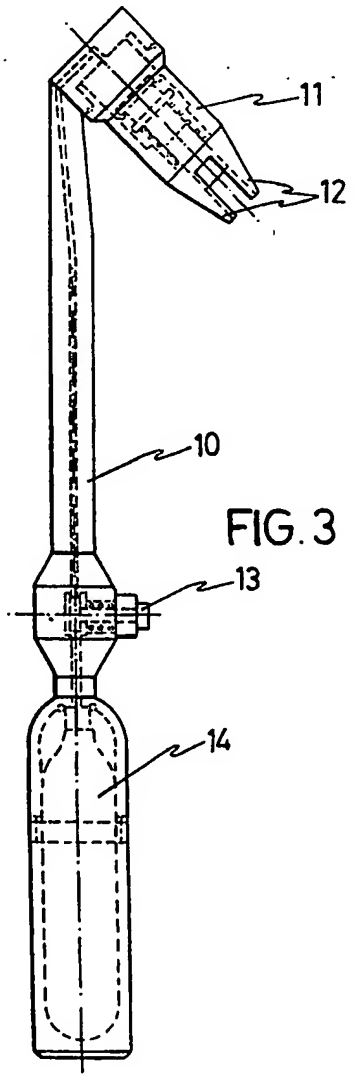

FIG. 3

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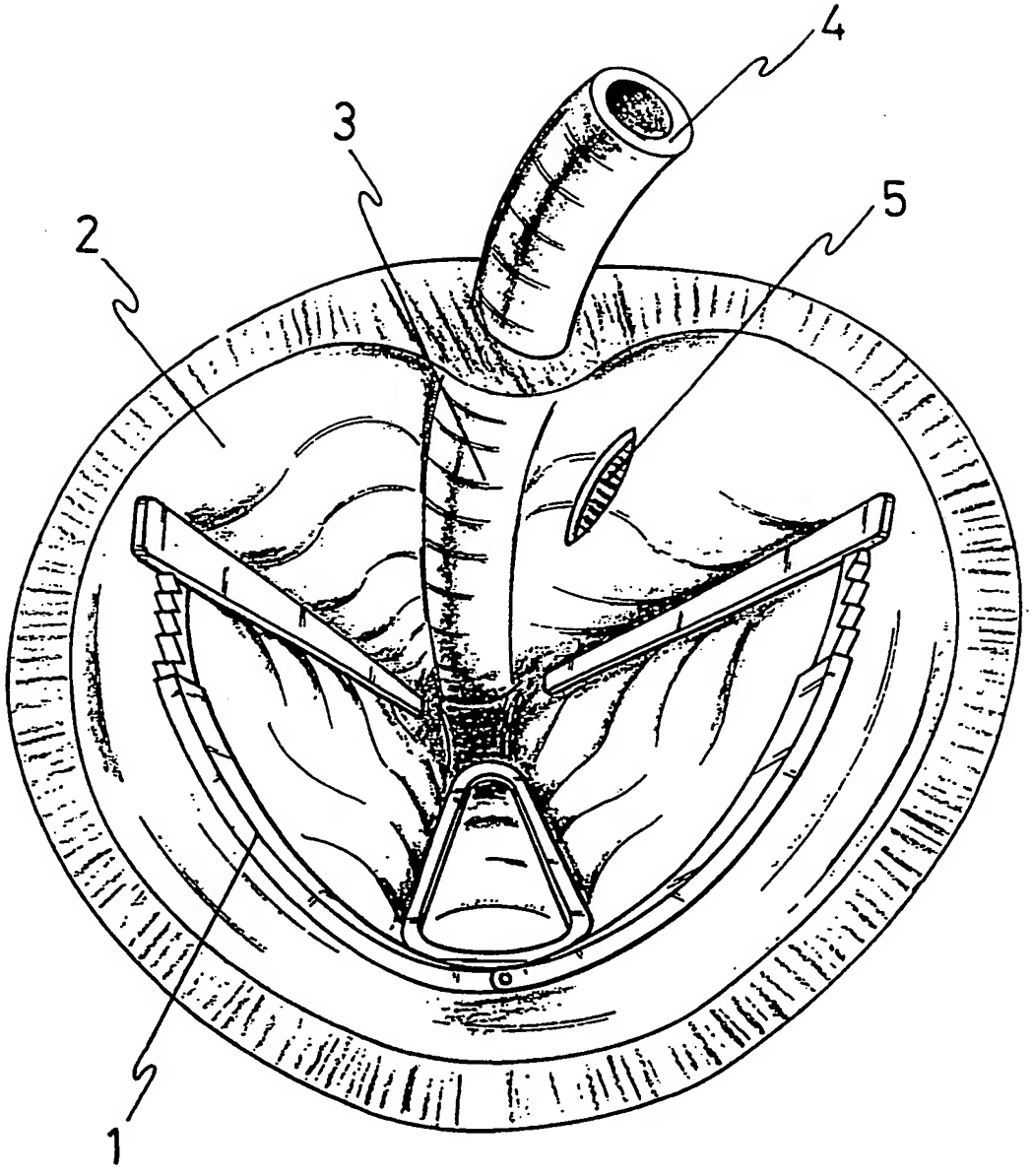

FIG. 1

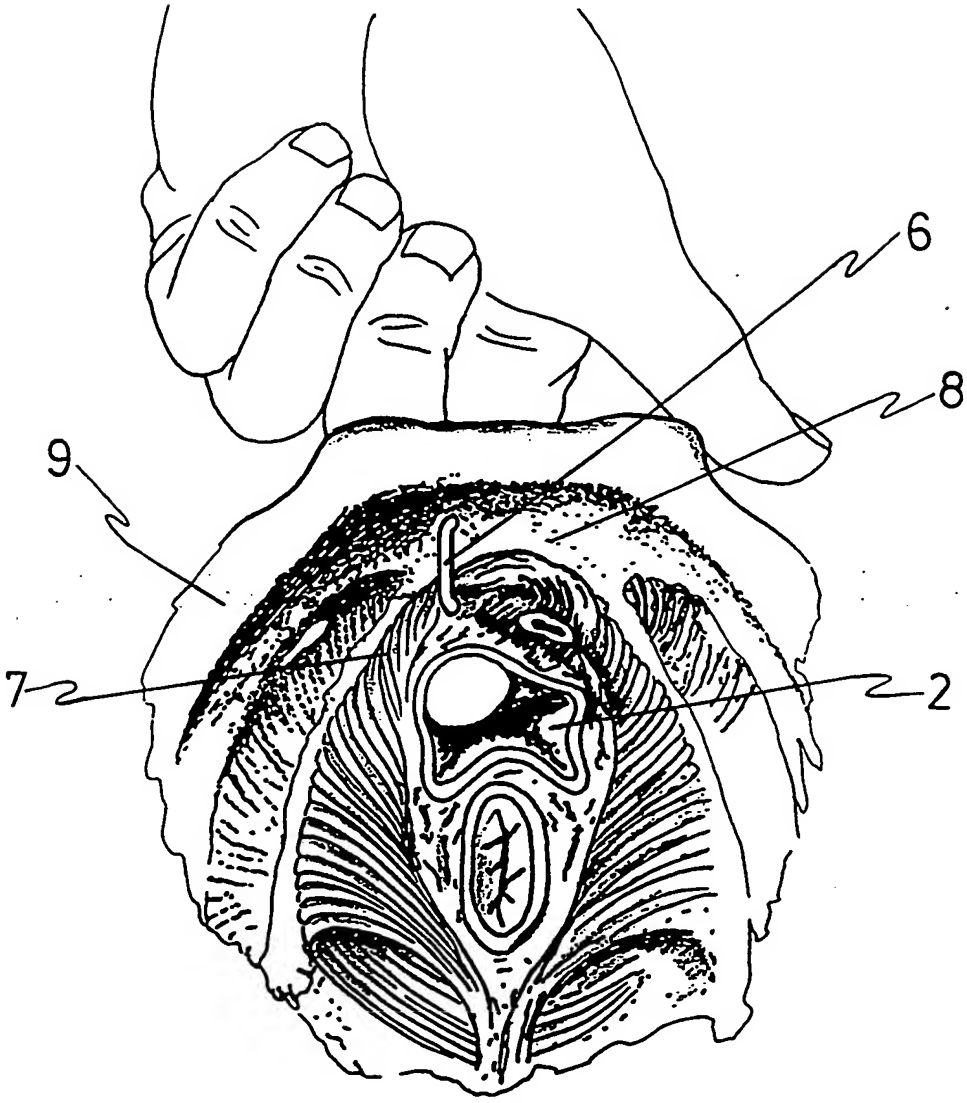

FIG. 2

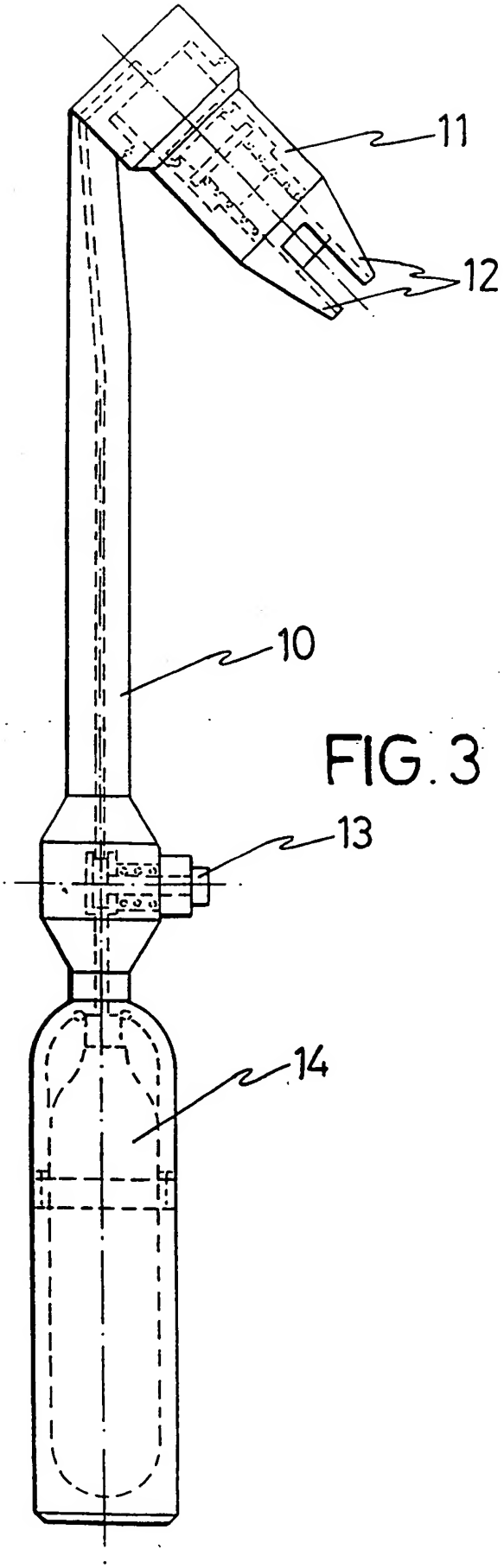

FIG. 3

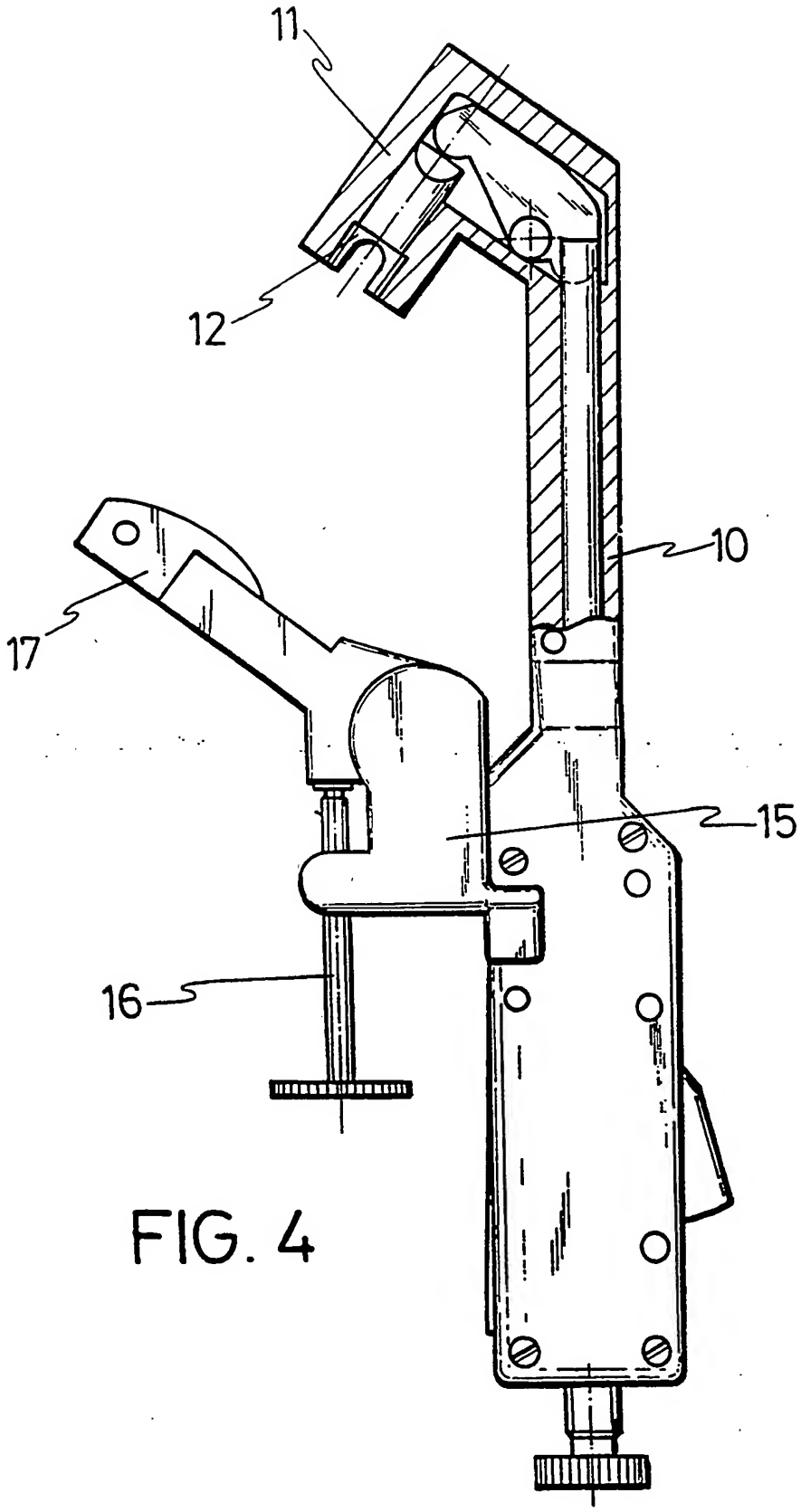

FIG. 4

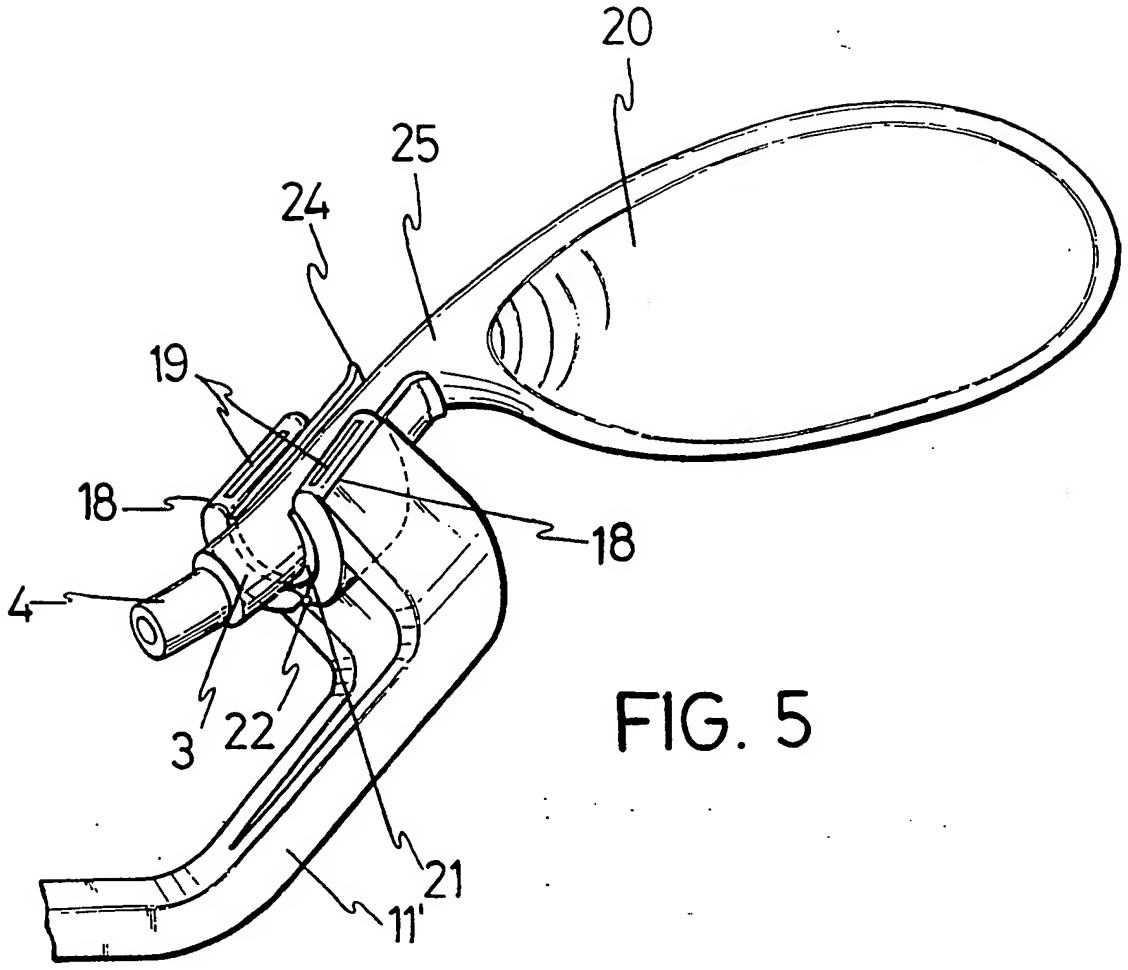

FIG. 5

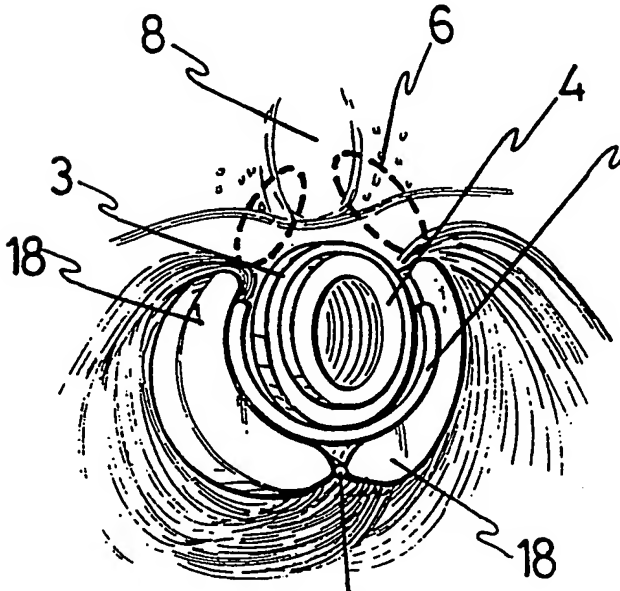

FIG. 6

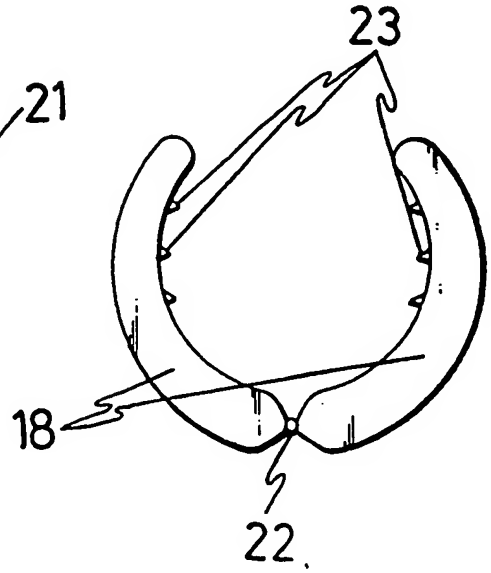

FIG. 7

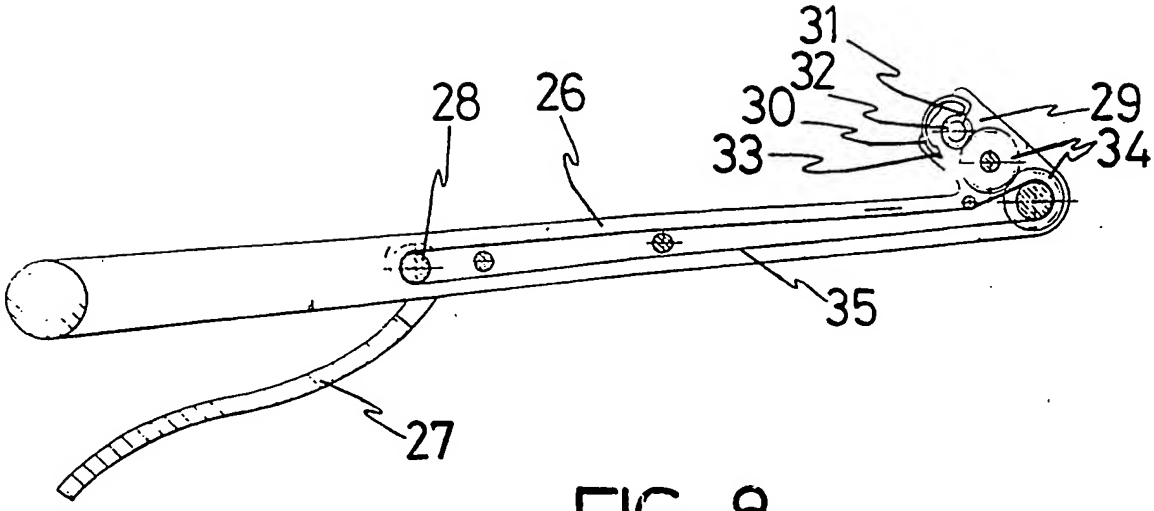

FIG. 8

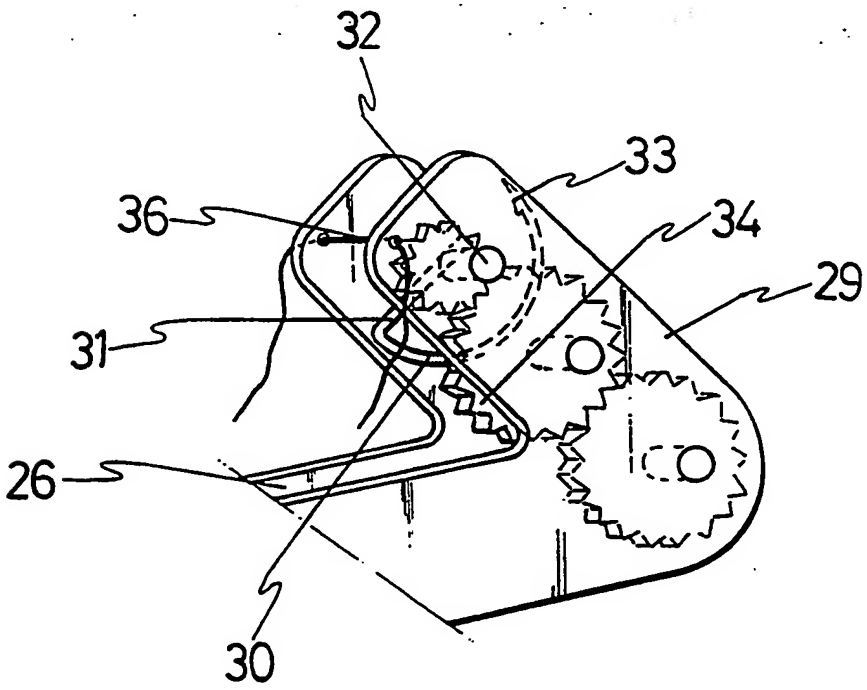

FIG. 9

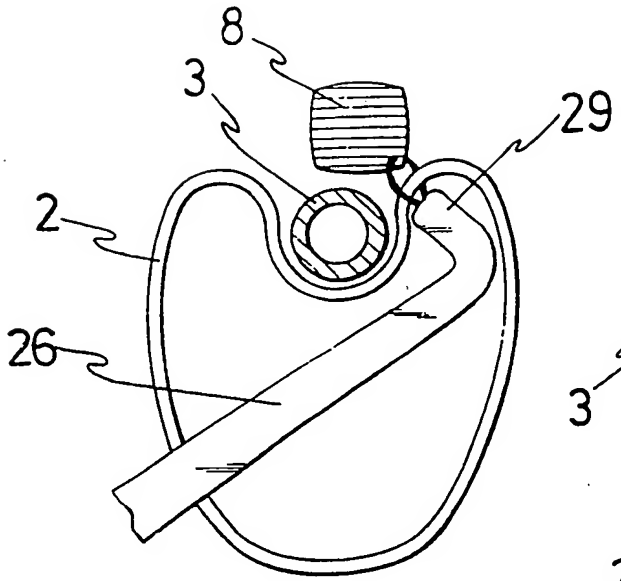

FIG. 10

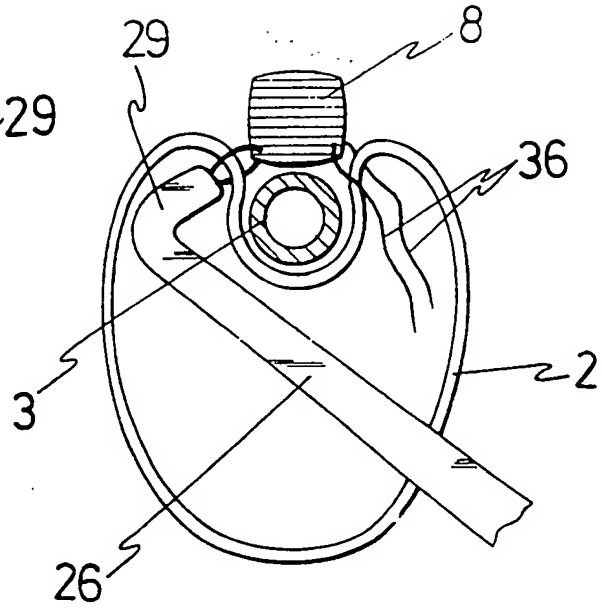

FIG. 11

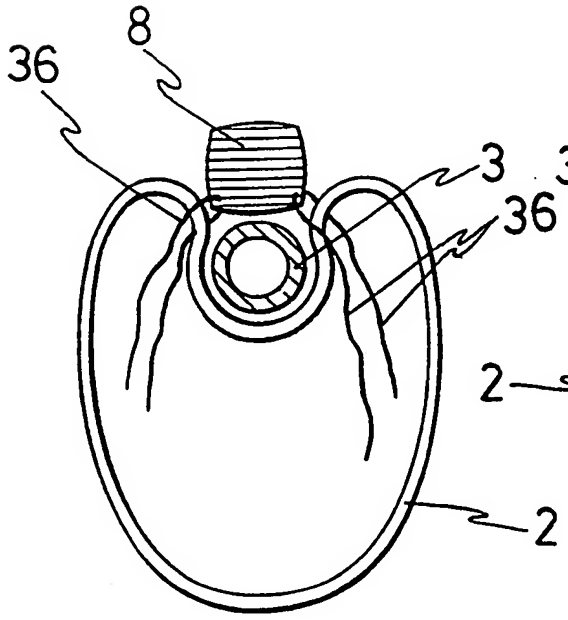

FIG. 12

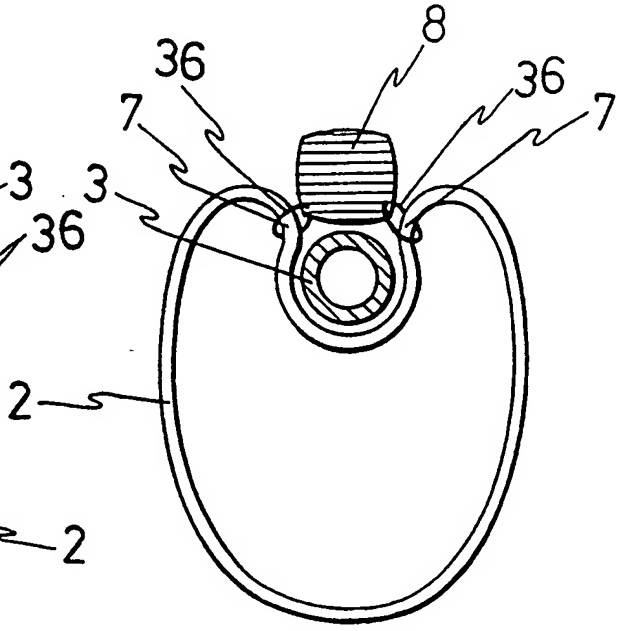

FIG. 13

VAGINAL AUTOSUTURE DEVICE TO AVOID URINARY INCONTINENCE IN WOMEN

OBJECT OF THE INVENTION

The invention refers to a vaginal autosuture device to avoid urinary incontinence in women, the device being foreseen to carry out by means of clamps or by means of threads connection between the para-urethral parts of the vagina and the corresponding cartilage of the symphysis pubica, for the purpose of fastening and maintaining these para-urethral areas of the vagina permanently raised and thus avoiding urinary incontinence in women.

The device by means of which the autosuture is carried out is comprised of an elongated body handled by the surgeon himself, whose end includes a head through which the release of clamps is carried out, or else the actuation of a needle to make the thread pass through the tissues corresponding to the para-urethral area of the vagina and the symphysis pubica, obtaining in the present case autosuture, and requiring in the second one the knotting of each thread to attain autosuture.

BACKGROUND OF THE INVENTION

As is known, the urethra has its own mechanisms that allow it to interrupt the wave of pressure that is received from the urinary bladder, when the intra-abdominal pressure that comes about suddenly and unexpectedly (for example, cough) acts upon the urinary bladder. The behavior of the anatomical elements that hold it in place are interpreted in very different manners by specialists.

In any case, when the protective mechanisms are changed (delivery and, basically, age) the urethra "descends", while the pelvic diaphragm becomes thinner reducing the urethral resistance, upon the contracting force with which the diaphragm and the sphincter contract being decreased. In this situation, the increased wave of vesical pressure is passed on by the urethra and,

depending on the degree of deterioration , the leakage of urine will be more or less abundant.

In order to correct this type of incontinence normally surgery has been resorted to, based on raising the urethra and creating an anchorage or inflexion point where the "folding" effect that interrupts the wave of pressure transmitted from the urinary bladder is produced.

There are many praised surgical procedures, some vaginal and other abdominal, there being others that are done through both the vagina and the abdomen, so that in all cases the surgical operation is complex.

DESCRIPTION OF THE INVENTION

The object of the invention has the purpose of solving urinary incontinence in women by means of a very simple and enormously effective system, based on carrying out a fastening of the side parts of the urethra upon the cartilage of the symphysis pubica, so that with the patient in a gynecological position and with a suitable vaginal separator, said vaginal cavity is spread open, exposing the roof of this organ where the urethra passes, examining afterwards the rears of the urethra and vagina which are the limits between the urethra and the vagina, which run all along the urethra itself. Afterwards, a vesical catheter is inserted through the urethra to better examine this duct and afterwards the mobility of the urethra is explored, detecting the cartilage of the pubis by the raised part that it normally has with regard to the bones that delimit it.

Consecutively, the fastening of each one of these side parts of the urethra is carried out by means of the device of the invention, which is comprised of a clamping device whose end or whose head through which the clamps are released will be placed against the posterior surface of the pubis, so that the actuation of said clamping device carries out the clamping of the clamp into the carti-

lage of the pubis, fastening in this way the urethra upon fastening the roof of the vagina on each side.

By means of the end of the clamping device one can detect or locate the cartilage of the pubis to fasten the urethra, on both sides, the clamping device being pneumatic, in other words, it is operated by compressed air and it will be provided with the corresponding push button actuation of which releases the clamp and clamps it into the cartilage of the pubis to which the wall of the vagina will remain fastened.

Logically, these clamps once clamped into place, will close to prevent them from coming loose.

Likewise, the cited clamps will produce in the tissues involved an adequate compressive effect to bring about the healing response of the tissues.

In the area where the clamps are going to be applied, it is necessary to make an incision with a scapel in the mucous membrane of the vagina so that upon inserting the clamp said clamp remains hidden behind said mucous membrane of the vagina.

Locating the cartilage can also be done by radioscopy, in which case the clamping device will be made out of a plastified material, and upon the clamp being made out of metal the point where the clamp itself is to be applied will be easy to locate. This second type of clamp will have an external device with a pressing effect to better fasten the mouth of the clamping device against the surface to be clamped, and so that the impact of the clamps is more effective and sure.

In a second embodiment it has been foreseen that the clamping device is completed with a channel adapted to the mouth of the clamping device for the purpose of protecting the urethra against strangulations or damage that can be caused in the clamping action, whose channel will logically go around the urethra, once the ure-

thra has been spread open after introducing a urethral catheter in the same.

Said channel has the particularity that the end that remains in the bottom part is broader in its caliber so that it can adapt to the funnel that the neck of the urinary bladder forms with regard to the urethra.

It is obvious that the element that comprises the cited channel makes the positioning of the clamping device easier, since the urethra is obligated by the channel and upon lifting the clamping device so that it approaches the pubis the neck of the urinary bladder will be lifted and moved in order to prevent it from being included in the thickness of the tissue that is going to be clamped.

Therefore, on the grounds of this second embodiment or channel with which the clamping device is complemented, a correct positioning of said clamping device is achieved, upon having a better reference upon positioning the clamping device with regard to the urethra, whereby the clamping will be more exact.

It has also been provided for that in this second embodiment the clamping device is provided with a double mouth for the purpose of simultaneously applying two clamps, one on each side of the urethra, in such a way that one mouth of the clamping device will remain on one side of the channel and logically the other one will remain on the other side, said mouths being oriented angularly with regard to the middle line, in direction to the cartilage of the pubis, thus making the operation easier, on the contrary to that which would happen with the clamping device with a single mouth by means of which two operations would be necessary to apply the two corresponding clamps.

On the other hand, these heads of the clamping device, aside from being tiltable with regard to the central chan-

nel, will have side grooves or striae that permit the positioning of the channel at different heights, in other words, the position thereof will be able to be varied in order to remain closer or farther away from the pubis, to keep the urethra spacious.

In a third embodiment, the autosuture device is foreseen so that the autosuture is done by means of thread instead of clamps, the device being provided in the end of its head with a semicircular needle that is rotated by means of an internal mechanism, such as a transmission based on a chain and pinions for example, upon manual operation of an external lever, all in such a way that the needle turns and its end describes an arc that in one direction perforates the vaginal wall and the tissue forming the symphysis pubica, while turning in the other direction involves the threading and pulling of the thread which, previously placed in a suitable area of the head of the device, is clasped by said semicircular needle, upon the needle having a type of notch in its end, in such a way that by means of the notch, in the direction considered as a recoiling in the turning of the needle, the clasping and pulling of the thread that will be made to pass through the holes that the needle has previously made in its advance rotation are carried out.

In this way, carrying out the operation on both sides of the urethra, the two ends of the thread will remain entering and coming out through the openings that the needle has marked in its path, knotting afterwards.

As it is easy to infer, the tightening of the autosuture can be guaged since upon the two ends of the thread remaining loose, before knotting, tightening to a greater or smaller degree can be done and therefore an adjustment of the tightening will be achieved, which obviously implies an advantage over the autosuture done with a clamping device wherein no adjustment nor pre-tightening can be

done.

DESCRIPTION OF THE DRAWINGS

In order to complete the description that is going to be made hereinafter and for the purpose of providing a better understanding of the characteristics of the invention, the present specification is accompanied by a set of drawings on the grounds of whose figures the innovations and advantages of the device made in accordance with the object of the invention will be more easily understood.

Figure 1.- It shows a representation corresponding to the spreading open of the vaginal cavity done by means of a separator provided for this purpose, likewise representing in this figure the incision in one of the sides of the urethra, in whose incision precisely the corresponding clamp will be applied by means of the device of the invention.

Figure 2.- It shows a general perspective view of the inside of the vaginal cavity where one can see one of the two clamps that are to fasten the sides of the urethra to the pubis.

Figure 3.- It shows a longitudinal and schematic view of the device that comprises the metal clamping device for carrying out the surgical autosuture that forms part of the object of the invention.

Figure 4.- It shows the clamping device made out of transparent plastic material, it being actuated mechanically to release the clamps.

Figure 5.- It shows a representation according to a general perspective view of the head of the clamping device in its second embodiment, in other words, provided with the urethra support channel, also showing the catheter and the corresponding urinary bladder.

Figure 6.- It shows a front perspective view of the clamping device represented in the previous figure,

supporting the urethra fastening channel, as well as the clamps in dash lines.

Figure 7.- It shows a detailed view of the double head of the clamping device represented in the two previous figures, with the corresponding internal striae to permit the positioning of the corresponding urethra support channel at different heights.

Figure 8.- It shows a longitudinal sectional view of the device in another embodiment, foreseen so that the autosuture is done by means of thread, the head of the device having for this purpose a semicircular needle that is rotated and operated by means of a mechanism based on pinions and a chain, actuated by a hand control.

Figure 9.- It shows a detailed view of the head of the device represented in the previous figure, where one can clearly see the assembly of the needle and a possible positioning of the thread to be clasped by the end of the needle.

Figures 10, 11, 12 and 13. They show other schematic views of what can be considered the vagina, urethra and one part of the cartilage of the symphysis pubica, said figures showing the different stages to carry out the autosuture between the vaginal cavity and the cartilage of the symphysis pubica, on both sides of the urethra, and whose autosuture is done by means of the device represented in figures 8 and 9.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In view of the cited figures, and alluding first of all to figures 1 and 2, for use of the device by means of which the autosuture is going to be done, it is necessary to place the patient in a gynecological position first of all, so that by means of a vaginal separator (1), formed by a body with two arms hinged together and connected in common to a positioning element, as is represented in figure 1, the vaginal cavity (2) is spread open,

exposing the roof of the vaginal cavity where the urethra (3) passes, examining afterwards the rears of the urethra and vagina which are the limits between the urethra and the vagina, which run all along said urethra (3.)

Afterwards a vesical catheter (4) is inserted through the urethra itself (3), to better examine this duct, exploring afterwards the mobility of the urethra, which is easier to examine as the catheter (4) is incorporated, it being possible to detect the cartilage of the pubis by the raised part that it normally has with regard to the bones that delimit it.

In figure 2, the exploration and even a clamp (6) fastened to one of the sides of the urethra (3) can be seen, the clamp (6) that will remain contained in an incision (5) made with a scapel in the suitable area, to achieve that the clamp (6) is hidden, it being possible to see in figure 2 how said clamp (6) raises the area corresponding to the para-urethral tissue (7) and holds it in that raised position upon the other end of the clamp (6) clamping into the pubic ligament corresponding to the bone of the pubis (9), in other words, in the tissue that forms the symphysis pubica.

In figure 3 the clamping device by means of which the above cited autosuture is carried out is seen, so that this clamping device is comprised of an elongated body provided in one of its ends with a head (11) that forms an angular extension with regard to the horizontal axis of the body (10) of the clamping device, and whose head (11) will rest on the above cited previously located points, that correspond to those of making the incisions (5), for which purpose that head (11) of the clamping device will slide over the posterior wall of the pubis to detect the raised part of the cartilage of the symphysis pubica, and once this operation has been carried out and having the sensation that the cartilage has been detected,

before inserting the clamp (6) the clamping device will be removed and the incision (5) will be made with the scapel, incision that is made in the mucous membrane of the vagina, right in the place where the mouth corresponding to the head (11) of the clamping device (10) rests, with the intention that upon inserting the clamp (6) said clamp remains hidden behind the mucous membrane of the vagina.

Therefore, the ends (12) of the head (11) of the clamping device will be inserted in the bed formed by the incision (5) going over the bone of the pubis until the cartilage of the symphysis pubica is found again and in this position by means of a push button (13) the corresponding clamp (6) will be released, joining or fastening the wall itself of the vagina to the cited cartilage.

The clamping device shown in figure 3 is operated pneumatically, including for this purpose an inside carboy (14) in its corresponding handle, so that the pressure of the gas contained in the carboy releases the corresponding clamp (6) and the clamp clamps into the cited area.

In figure 4 a clamping device (10) that will be made out of transparent plastic is seen and it will make it possible to locate the area where the clamp (6) is to be placed, upon the clamp being made of metal, with the help of radiographic amplifying equipment so that under the control of radioscopy the effective end (12) of said clamping device (10) is viewed, logically this end will have the clamp and as the same is made out of metal the same is easy to locate , leading same to the transparent space between the bones of the pubis that correspond to the cartilage of the symphysis pubica. Once this position has been reached an element or mechanism that is assembled upon the clamping device itself and that is a pressing mechanism will be actuated, permitting the

gripping of the cartilage of the pubis. This mechanism is comprised of a fastening support (15), to which the pressing element itself (17) is connected, this pressing device being adjustable by means of a manual operating screw.

In a second embodiment, as is seen in figures 5, 6 and 7, the clamping device includes a head (11') divided into two parts or identical heads (18), each one of them provided with a outlet mouth for the corresponding clamp (6), all so that by means of this embodiment it is possible to simultaneously apply the two clamps, one on each side of the urethra (3), and the urethra having inside it the corresponding catheter (4), and continuing, as is seen in figure 5, in the corresponding urinary bladder (20.)

The heads (18) referred to and shown in figures 5, 6 and 7, and therefore the corresponding outlets (19) remain located one on each side of a channel (21) located between said heads (18), supporting these heads, with the particularity that said heads (18) are connected together by means of a bottom hinge (22), including on the inside surfaces thereof some longitudinal striae (23) that permit the channel (21) to be positioned higher or lower, in order to bring it close to or leave it more distant from the urethra itself (3.)

This channel (21) remains surrounding the urethra itself (3) as is clearly seen in figure 6, offering the end of the channel an expansion (24) in order to adapt to the funnel (25) that the neck of the urinary bladder (20) forms with regard to the urethra (3.)

In this way simultaneous application of the two clamps (6) one on each side of the urethra (3) can be carried out, with a direction as is represented in figure 6, whose clamps (6) will fasten upward the paraurethral tissue of the vagina to th symphysis pubica

or cartilage of the pubis (8.)

On the grounds of all of the above, in other words, in connection with the embodiment shown in figures 5, 6 and 7, one manages to apply the clamps (6), carrying out all the operations without the urethra (3) being strangled, since the channel (21) located between the heads (18) will prevent it, aside from permitting the simultaneous application of the two clamps (6.)

In a third embodiment, represented in figures 8 to 13, the device of the invention is comprised, as in the previous cases, of an elongated body (26) with a manual operating control (27), like a lever, that emerges from the side part of said body (26), the lever (27) being hinged in a transversal shaft (28.)

The body (26) includes the corresponding end head (29) that likewise forms an angle with the horizontal axis of this body, and in whose head a semicircular shaped needle (30) is mounted so as to turn in either direction, and one of whose ends extends into a straight section (31) through which it is fastened to a rotation shaft (32), while at the other end the needle (30) has a notch defining a clasping end (33) as will be put forth later on.

The device includes inside a system to carry out the turning of the needle (30), the system being based on a set of crowns or gears (34) that are operated by a chain (35) which in turn is geared to a pinion assembled on the shaft itself (28), in such a way that actuation of the lever (27) entails rotation of this shaft (28) and therefore the pulling of the chain (35) that will make the gear mechanism (34) turn carrying out the turning of the shaft on which the needle (30) is assembled.

With the device described corresponding to the embodiment shown in figures 8 and 9, the autosuture is done by means of a thread (36), which will replace the above cited clamps (6), in such a way that this thread (36)

duly positioned in the head (29) of the device or body (26), and with the correct positioning of the head in the same way as it has been said above, actuation of the lever (27) will carry out the turning of the needle (30) in one direction, turning which will be sectorial until the end (33) surpasses the thread (36), to later carry out the turning in the opposite direction, in which case the end (33) of the needle (30) clasps, by means of the notch provided for in that end (33), the thread (36) pulling it and making it pass along the path followed by the needle (30), and specifically by its end (33), so that this path is followed, as it has been said above, through each one of the areas collateral to the urethra (3) and through the cartilage (8) of the symphisis pubica, as is clearly represented in the different stages shown in figures 10, 11, 12 and 13.

In other words, what the device does is that by means of the needle (30) provided for in the head (29) of the same, it makes a suture thread (36) pass through the para-urethral area (7) of the vagina (2) and through the cartilage (8) of the symphisis pubica.

As is seen in figures 10, 11, 12 and 13 the operation is carried out on each side of the urethra (3), so that with the turning of the needle (30) in one direction and the other, as it has already been said above, the thread (36) passes through the holes made in the path of the end (33) of the needle (30), the ends of the thread (36) remaining free to be subsequently knotted.

Now then, before the first thread (36), placed on one side of the urethra (3) , is knotted, it is necessary to make the second thread pass to the other side of said urethra, just as it is shown in figure 12, so that once the two threads (36) have passed through the respective areas of the wall of the vagina and of

the cartilage of the symphysis pubica the same will be knotted, it being possible to adjust the tightening by simply tensing to a larger or smaller degree, by simple pulling of the ends of the thread (36.)

The fact that the thread (36) is not knotted until the other one has been put in place, is because that in order to carry out the operation it is necessary to move the urethra (3) towards the opposite side, operation that can be done with the thread unknotted, since if it were knotted, side movement of said urethra (3) could not take place.

The semicircular needle (30) can be placed in the position shown, effecting the turning of said needle in such a way that its end goes along the path from top to bottom, or else upon being located in the opposite position, in which case the end of said needle will go along the path from bottom to top.

CLAIMS

1.- Vaginal autosuture device to avoid urinary incontinence in women, which having the purpose of joining through the vagina the para-urethral tissue of the vagina to the symphysis pubica, and specifically to the connecting cartilage, effecting a spreading open of the vaginal cavity (2) by means of a separator (1), as well as exploration of the mobility of the urethra (3) in order to detect the cartilage (8) of the pubis (9), and the autosuture being foreseen to achieve the fastening of the roof of the vaginal wall (2) of each side of the urethra (3) to the part of the cartilage (8) corresponding to the posterior surface of the pubis (9), essentially characterized in that upon being comprised of an elongated body (10, 26) extended by one of its ends into a head (11, 29) that forms an acute angle with the elongated body defining the means to grip the body by hand; with the particularity that in the inside of said body means have been provided for, whose actuation by means of a push button or lever (13, 27), provides the suitable movement so that the autosuture element (6, 36) passes through the para-urethral tissue (7) of the vagina and of the cartilage (8) corresponding to the symphysis pubica, fastening the para-urethral areas of the vagina (2) raised up.

2.- Vaginal autosuture device to avoid urinary incontinence in women, according to claim 1, characterized in that the elongated body (10) of the device with its corresponding head (11) constitutes a pneumatically operated clamping device, storing in its head (11) the corresponding clamps that are released through the ends (12) of said head, after actuating by hand the push button (13) provided for in the elongated body (10) of the clamping device.

3.- Vaginal autosuture device to avoid urinary incontinence in women, according to claim two, characteri-

zed in that the clamping device (10) is comprised of a transparent plastic material, making it possible to apply the clamp (6) under the orientation of radioscopy, with the particularity that a pubis pressing mechanism can be assembled on the body (10) of the clamping device, this mechanism being comprised of a support (15) through which the assembly of the same on the body (10) of the clamping device is done, support (15) which includes the corresponding pressing element (17) that is pushed by a manual operating screw (16.)

4.- Vaginal autosuture device to avoid urinary incontinence in women , according to the above claims, characterized in that the head of the clamping device is comprised of an element (11') in which two parts or heads (18), each one of which provided with an outlet mouth (19) for the respective clamps (6), are formed, there being a channel (21) for positioning and supporting the corresponding urethra (3); it being provided for that said heads (18) are connected together by means of a bottom hinge (22), the mouths (19) of the heads having a converging slant in order to apply the corresponding clamps (6) with a specific angulation that permits the correct fastening of the para-urethral tissue to the cartilage of the pubis.

5.- Vaginal autosuture device to avoid urinary incontinence in women, according to claim 4, characterized because the channel (21) located between the heads (18), has in its outside end an expansion (24) to adapt to the funnel (25) that forms the neck of the urinary bladder (20) with regard to the urethra (3.)

6.- Vaginal autosuture device to avoid urinary incontinence in women, according to claims 4 and 5, characterized in that the heads (18) include in their inside surface some projections (23) that permit the positioning and retaining at different heights the channel (21), making it possible to reduce or increase the proximity

of the outlet mouths (19) of the clamps (6) keeping the urethra (3) without strangulation.

7.- Vaginal autosuture device to avoid urinary incontinence in women, according to claim 1, characterized in that the head (29) of the elongated body (26) includes in its end a semicircular needle (30) that, through a straight arm (31) with internal radial orientation to the arc of the needle (30), it is connected to a shaft (32) capable of turning sectorially in both directions, so that the turning in one direction involves the end (33) of the cited needle (30) emerging through the mouth of the head (29) and perforating the corresponding paraurethral area (7) of the vagina (2) and the cartilage (14) of the symphysis pubica, with the particularity that in the opposite direction of rotation of this needle (30), a notch shape provided for in the end itself (33) of the needle, clasps and pulls the suture element formed by a thread (36) adequately located in the inside of the head (29) of the device (26), said thread (36) passing through the holes made by the needle (30) in its path.

8.- Vaginal autosuture device to avoid urinary incontinence in women, according to claim 7, characterized because the actuation means of the assembly shaft (32) of the needle (30), are comprised of a system of gears (34) and a chain (35) that is actuated by a pinion assembled on the rotation shaft itself of the manually operated lever (27.)

9.- Vaginal autosuture device substantially as herein before described with reference to the drawings herein.

Examiner's report to the Comptroller under Section 17
(The Search report)

Relevant Technical Fields

(i) UK Cl (Ed.L) A5R (RES)

(ii) Int Cl (Ed.5) A61B 17/04

Search Examiner
N A FRANKLIN

Date of completion of Search
12 OCTOBER 1993

Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii)

Documents considered relevant following a search in respect of Claims :-
1-9

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages	Relevant to claim(s)
X	GB 1243808 (US SURGICAL) Note Figure 1	1 at least

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).